AUG 2 2012

Section 5 – 510(k) Summary for

Microsoft® Amalga™ UIS Image Processing Module

1. Submission Sponsor

Microsoft Corporation
1 Microsoft Way
Redmond, WA 98052
USA
Phone: 301.771.8624

Contact: Michael Willingham, VP, Quality Assurance & Regulatory Affairs

2. Submission Correspondent

Emergo Group
611 West 5th Street, Third Floor
Austin, TX 78701
Cell Phone: 262-290-0023
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Adrienne Lenz, Senior Consultant, QA & RA
Email: project.management@emergogroup.com

3. **Date Prepared**
17 July 2012

4. Device Name

Trade/Proprietary Name: Microsoft® Amalga™ UIS Image Processing Module
Common/Usual Name: Picture Archiving and Communication System
Classification Name: Picture archiving and communications system
Classification Regulation: 892.2050
Classification Panel: Radiology
Product Code: LLZ
Device Class: 2

FDA Establishment Registration #: 3007734659

5. Predicate Devices

K061214 AquariusAPS Server, TeraRecon, Inc.
K011142 AquariusAPS Workstation, TeraRecon, Inc.

6. Device Description

The Microsoft® Amalga™ UIS Image Processing Module (IPM) is used in conjunction with Microsoft® Amalga™ UIS and Microsoft® Amalga™ UIS Medical Imaging Module (MIM). These two software products (Amalga™ UIS and Amalga™ MIM) are Class 1 devices that perform consolidation of disparate health information (Amalga™ UIS) and medical image communication (Amalga™ MIM). Amalga™ IPM enables healthcare providers to rapidly navigate across images by selecting tagged organs and to review these images using multi-planar reconstruction (MPR).

Amalga™ IPM delivers a basic MPR rendering platform that constructs a three-dimensional view from a set of CT, MR, or PET images. Amalga™ IPM also enables organ label based navigation through DICOM CT scans both in 2D image display and MPR viewing mode.

Intended Use

The Microsoft® Amalga™ UIS Image Processing Module is used in conjunction with Microsoft® Amalga™ UIS and Microsoft® Amalga™ Medical Imaging Module to receive medical images from acquisition devices and imaging systems adhering to DICOM protocol. Medical images received from volumetric or planar imaging modalities are processed to derive certain information. The information thus derived is transmitted using the DICOM or HTTP protocol to other devices supporting these standard protocols.

The IPM enables physicians and other healthcare providers to rapidly navigate across images by selecting tagged organs and review them through multi-planar reconstruction (MPR). IPM is not intended to be used for primary diagnosis.

This device is not intended to be used for mammography.

7. Technological Characteristics and Substantial Equivalence

The following table compares the features of the Microsoft® Amalga™ UIS Image Processing Module to the AquariusAPS Server and Workstation, providing the basis of substantial equivalence.

Comparison Table

Trade Name	Amalga™ UIS IPM	AquariusAPS Server	AquariusAPS Workstation
510(k) Number		K061214	K011142
Product Code	LLZ	LLZ	LLZ
Regulation Number	21 CFR 898.2050	21 CFR 898.2050	21 CFR 898.2050
Regulation Name	Picture archiving and communications system	Picture archiving and communications system	Picture archiving and communications system
Platform	Amalga UIS 2009 R2 SP3 and Medical Imaging Module	TeraRecon	TeraRecon
Intended for use in primary diagnostic workflow	No	Yes	Yes
Receive images using DICOM protocol	Yes	Yes	Yes
Send images using DICOM protocol	Yes	Yes	Yes
MPR Visualization (Axial/Sagittal/Coronal)	Yes	No	Yes
MPR Visualization (oblique)	Yes	No	Yes
Modalities supported for MPR review	CT, MR, PET	CT, MR, PET	CT, MR, PET

Trade Name	Amalga™ UIS IPM	AquariusAPS Server	AquariusAPS Workstation
Identify locations of anatomical structures	Yes. The list of the structures are: • Abdomen, • Adrenal Gland (Left/Right), • Femoral Neck and head (Left/Right), • Heart (Atrium and ventricle) (Left/Right), • Kidney (Left/Right), • Liver, • Lung (Left/Right), • Pelvis, • Spleen, • Stomach, • Thorax	Yes. The list of structures are: • Brain • Heart • Heart vasculature • Liver • Lung	Yes (manual)
Modalities supported for identification of anatomical structures	CT	CT	CT
Manual review of identified anatomical structures and correction tools	Yes	Yes	Yes
Ability to navigate to an image displaying an identified anatomical structure	Yes	Yes	Yes
Align and review two or more sets of images side by side	Yes. Link by image number for two series	Yes	Yes
Performing actions and image set navigation based on DICOM and other data identified from the DICOM image set	Yes	Yes	No

8. Non-Clinical Testing

Support for the substantial equivalence of the Microsoft® Amalga™ UIS Image Processing Module was provided as a result of risk management and software validation, which confirmed all features of the Microsoft® Amalga™ UIS Image Processing Module were compliant with the software requirements. The Microsoft® Amalga™ UIS Image Processing Module operates properly for multiplanar reconstruction and navigation using semantic tagging of organs.

9. Clinical Testing

Validation of the image tagging algorithm was completed using human images from a variety of databases. These databases comprise patients with a wide variety of medical conditions and body shapes and the scans exhibit large differences in image cropping, resolution, scanner type and use of contrast agents. Comparison between physician identified and software identified boundaries confirmed suitable accuracy and efficiency of the image tagging algorithm. Sensitivity, specificity, accuracy and precision were determined for each of the 21 organs. Accuracy ranged between 84% and 99%, exceeding the predetermined threshold of 81%.

10. Conclusion

It has been shown in this 510(k) submission that the difference between the Microsoft® Amalga™ UIS Image Processing Module and the predicate device does not raise any questions regarding its safety and effectiveness. The conclusions drawn from the nonclinical and clinical tests demonstrate equivalent performance of the Microsoft® Amalga™ UIS Image Processing Module and the predicate devices. The Microsoft® Amalga™ Image Processing Module, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

AUG 2 2012

Caradigm
% Ms. Adrienne Lenz
Senior Consultant, QA and RA
Emergo Group
611 West 5th Street, Third Floor
AUSTIN TX 78701

Re: K120734
Trade/Device Name: Microsoft® Amalga™ UIS Image Processing Module
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 17, 2012
Received: July 18, 2012

Dear Ms. Lenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K120734

Section 4 - Indications for Use Statement

510(k) Number (if known): Not Assigned

Device Name: Microsoft® Amalga™ UIS Image Processing Module

Indications for Use:

The Microsoft® Amalga™ UIS Image Processing Module (IPM) is used in conjunction with Microsoft® Amalga™ UIS and Microsoft® Amalga™ UIS Medical Imaging Module to receive medical images from acquisition devices and imaging systems adhering to DICOM protocol. Medical images received from volumetric or planar imaging modalities are processed to derive certain information. The information thus derived is transmitted using the DICOM or HTTP protocol to other devices supporting these standard protocols.

The IPM enables physicians and other healthcare providers to rapidly navigate across images by selecting tagged organs and review them through multi-planar reconstruction (MPR). IPM is not intended to be used for primary diagnosis.

This device is not intended to be used for mammography.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K120734